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Sealing means for ostomy appliances

Abstract:

A composite skin barrier including a first adhesive component which fits around a stoma, a coupling element, and a second adhesive component which is flexible, light and has a degree of porosity. The second adhesive component contacts the skin at a distance from the stoma.

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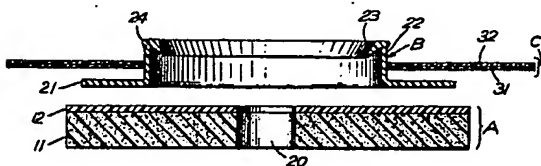
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(54) Sealing means for ostomy appliances.

(57) A composite skin barrier including a first adhesive component which fits around a stoma, a coupling element, and a second adhesive component which is flexible, light and has a degree of porosity. The second adhesive component contacts the skin at a distance from the stoma.



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TITLE MODIFIED
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A SKIN BARRIER

5 Major abdominal surgery for a number of diseases
involving different parts of the gastro-intestinal
and urinary tract can result in a patient being
left with an abdominal stoma. The three most
common types of abdominal stoma are the colostomy,
the ileostomy, and the ileal conduit. In the case
of an ileostomy, ileal conduit, and many colostomy
10 operations, the patient is unable to control
the passage of bodily waste material and must rely
upon an appliance attached to their body to
collect this material.

15 Numerous appliances have been proposed for
this purpose. Most can be characterized as either a
one-piece or a two-piece system. The one-piece
appliance conventionally consists of a pouch having
an opening in one sidewall for the stoma around
which a plastic faceplate is permanently bonded.
20 The faceplate includes an outer layer of
adhesive material which is designed to affix the
appliance directly to the body or to an inter-
mediate skin barrier or sealing washer. The two-
piece appliance conventionally consists of a
25 mounting ring that is supported on the body by

Recently, a two-piece appliance disclosed by Steer et al. in British Patent 1,571,657

20 Preferred embodiments of the invention will now be described by way of example with reference to the drawings in which:-

25 Figure 2 is a front view taken along line 2-2
of figure 1.

30 Figure 4 is a front view of an ostomy pouch
having a coupling element enabling it to be affixed
to the skin barrier shown in figures 1 to 3.

Figure 5 is an enlarged section taken in a vertical plane of the pouch coupling element.

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Figure 6 is an exploded view similar to figure 3 of an alternate embodiment of the composite skin barrier of this invention.

5 This invention is directed to a composite type skin barrier product which includes a coupling element to which a pouch can be easily and securely attached. This skin barrier has improved flexibility and is lighter and more comfortable on the body
10 than those currently employed. As a result of its increased flexibility, the skin barrier provides a stronger bond with the skin and is not subject to cracking, creasing, or lifting as the anatomy underneath bends or stretches.

15 The composite skin barrier of this invention includes a first adhesive component which fits around the stoma, a coupling element, and a second adhesive component which is flexible, light, and a degree of porosity or breathability.

20 In the preferred embodiment, the coupling element is permanently affixed to the top of the first adhesive component around the stomal opening and the second adhesive component overlaps a flange portion of the coupling element and any
25 exposed top portion of the first adhesive component which is exterior to the coupling element.

 In an alternative embodiment, the porous adhesive component is bonded to the top of the first adhesive component and the coupling element is
30 affixed directly to the second adhesive component.

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Referring to figures 1 - 3 in more particular detail, the composite skin barrier 10 consists of three components. Component A includes an adhesive layer 11 and an outer polymeric film 12 and is shown with a centrally located opening or starter hole 20 which can be enlarged to fit snugly around a stoma. Component B is a coupling element which is permanently affixed to outer polymeric film 12. Component C is a flexible microporous tape having an adhesive layer 31 that overlaps flange portion 21 of the coupling element and any of polymeric film 12 not affixed to flange 21. Outer surface 32 of the microporous tape is a porous backing layer. In use, adhesive surface 31 is pressed onto the body a distance from the stoma and aids adhesive layer 11 in maintaining the skin barrier in place. Component A may extend exactly to the end of flange 21 of component B or slightly beyond as shown in figures 1 to 3.

The adhesive layer 11 is a homogeneous blend of one or more pressure sensitive adhesive materials having intimately dispersed therein one or more water soluble hydrocolloid gums. Optionally, one or more thermoplastic elastomers can be included with the pressure sensitive adhesive materials and one or more water swellable or inert cohesive strengthening agents can be included with the hydrocolloid gums.

Suitable pressure sensitive adhesive materials for inclusion in adhesive layer 11 are various natural or synthetic viscous or elastomeric

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substances such as natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, polyisobutylene, etc., either possessing dry tack by themselves or developing such tack upon the addition of a plasticizer. Low molecular weight polyisobutylenes having a viscosity average molecular weight of from about 36,000 to about 58,000 (Florey) possessing pressure sensitive adhesive properties are preferred. Such polyisobutylenes are commercially available under the trademark Vistanex from Exxon as grades LM-MS and LM-MH. One or more thermoplastic elastomers can optionally be included with the pressure sensitive adhesive substances in order to impart the properties of rubber-like extensibility and both rapid and complete recovery from modular strains. Suitable thermoplastic elastomers include medium molecular weight polyisobutylenes having a viscosity average molecular weight of from about 1,150,000 to 1,600,000 (Florey), butyl rubber which is a copolymer of isobutylene with a minor amount of isoprene having a viscosity average molecular weight of from about 300,000 to about 450,000 (Florey), and styrene copolymers such as styrene-butadiene-styrene (S-B-S), styrene-isoprene-styrene (S-I-S), and styrene-ethylene/butylene-styrene (S-EB-S) which are commercially available, for example, from Shell Chemical Co. under the trademark Kraton as Kraton D1100, Kraton D1107, Kraton 4000, Kraton G1600, and Kraton G4600. Preferred thermoplastic elastomers are butyl rubber having a viscosity average molecular weight of about 425,000 (commercially available as grade 077),

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polyisobutylene having a viscosity average molecular weight of about 1,200,000 (commercially available under the trademark Vistanex from Exxon as grade L-100), and styrene-isoprene-styrene (S-I-S) copolymers (commercially available from Shell as Kraton D 1107).

The pressure sensitive adhesive component including the optional thermoplastic elastomer is present at from about 30% to about 70% by weight of adhesive layer 11, preferably from about 40% to about 50% by weight. The thermoplastic elastomer can be employed at up to three times the weight of the pressure sensitive elastomeric substances but preferably the thermoplastic elastomer if present will be at from about 20% to about 40% by weight of the pressure sensitive elastomeric substance.

Suitable water soluble hydrocolloids for inclusion in adhesive layer 11 are sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya. These gums impart wet tack, i.e., the ability to adhere to moist surfaces, to adhesive layer 11. One or more water swellable cohesive strengthening agents can optionally be included with the water soluble hydrocolloids in order to control the rate of hydration of water soluble gums. Suitable cohesive strengthening agents include finely divided substantially water insoluble cross-linked sodium carboxymethylcellulose, finely

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5 divided substantially water insoluble starch-acrylonitrile graft copolymer such as that described in U.S. Patent 3,661,815, finely divided substan-

10 tially water insoluble cross-linked dextran such as that commercially available under the trademark Sephadex, finely divided purified wood cellulose such as that commercially available under the trademark Solka-Floc, and finely divided inert natural or synthetic fibrous material such as cotton.

15 The water soluble hydrocolloids and the optional water swellable or inert cohesive strengthening agents together are present at from about 35% to about 65% by weight of adhesive layer 11, preferably from about 45% to about 60% by weight.

20 Polymeric film 12 is laminated onto the surface of adhesive layer 11 and is a thin continuous or discontinuous film of polymeric material such as polyethylene, polypropylene, polyurethane, polyvinylchloride, etc. In component A, the adhesive layer 11 will vary in thickness from about 10 to about 120
25 mils and the film 12 will vary in thickness from about 1 to about 10 mils.

30 Small amounts, i.e., less than about 10% by weight of the adhesive layer 11, of other ingredients may be included in the adhesive layer 11. For example, a plasticizer such as mineral oil, an antioxidant such as butylated hydroxyanisole, a

deodorant or perfume agent may be included.
In addition, small amounts of a pharmacologi-
cally active ingredient can be included in
the adhesive composition. For example, an
antibiotic or antimicrobial agent such as
neomycin, an antiseptic agent such as
povidone iodine, or antiinflammatory
agent such as hydrocortisone or triam-
cinolone acetate.

Component A is prepared as follows. A premix
is prepared of the water soluble gums, water
swellable or inert cohesive strengthening agent and
any other optional substances. The premixed
powder is then placed in a heavy duty high shear
sigma blade or equivalent type mixer. The
viscous pressure sensitive adhesive component is
then added in two or three equal segments.
Mixing is allowed to proceed for approximately
ten minutes between each addition of the viscous
material. The resultant dough-like mass is
then extruded or rolled or pressed to desired
thickness. In working with large batches of
material, the dough-like mass may be kneaded
prior to the extrusion step. Alternatively,
the process may be varied by first working the
viscous pressure sensitive adhesive material
in the mixer for about ten minutes and then
adding the powder premix to two or three equal
segments with agitation for about 15 minutes
between each addition. When the pressure

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sensitive adhesive component includes an amount of optional thermoplastic elastomer, such elastomer is first blended by geometric dilution with the pressure sensitive adhesive material in a heated high shear sigma blade or equivalent type mixer. Polymeric film 12 is then laminated onto one side of the adhesive layer and silicone coated release paper on the other to form large slabs or a continuous web of the adhesive laminate. Component A of desired configuration including starter hole 20 are then die cut.

Component B is a coupling element. Preferably, the coupling element (as best shown in figure 3) is in the form of a cylindrical rib 22 extending substantially perpendicularly from a flat flange 21 and includes a thin resilient flexible and deflectible seal strip 23. As shown, the seal strip 23 is of tapering form seen in cross-section and extends at an angle radially inwardly from an inner surface of rib 22. Another surface of rib 22 may be provided as shown with a peripheral rim 24. Coupling B is formed from any suitable polymeric material such as polyethylene, polypropylene, etc., and is permanently affixed to the surface of polymeric film 12 by heat sealing, ultrasonic welding, by impulse welding, or by use of adhesives. Of course, coupling element B is affixed to film 12 so as to surround starter hole 20.

Component C consists of microporous adhesive layer 31 and a porous backing layer 32. The term microporous is used since the surface of adhesive layer 31 appears to be continuous but when viewed under a microscope the adhesive layer is revealed

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to be sponge-like having randomly located channels and voids.

5 The microporous adhesive layer can be of the acrylic type as taught by Copeland in U.S. Patent 3,121,021. However, preferably, the adhesive layer 31 is made of the same ingredients as adhesive layer 11 with the microporosity resulting from a difference in the manner of processing. Thus, adhesive layer 31 is preferably
10 a homogeneous blend of one or more pressure sensitive viscous or elastomeric materials having intimately dispersed therein one or more water soluble hydrocolloid gums and optionally including one or more thermoplastic elastomers and/or one
15 or more water swellable cohesive strengthening agents. In addition to the various minor optional ingredients such as antioxidants, preservatives, plasticizers, etc., which can be incorporated in either adhesive layer 11 and 31, adhesive layer 31 also can include up to 25%
20 by weight of a tacifier such as terpene resin.

 Preferably, adhesive layer 31 includes as the pressure sensitive adhesive and thermoplastic elastomer a mixture of a low molecular weight poly-
25 isobutylene (grade LM-MH or LM-MS) and a medium molecular weight polyisobutylene (grade L-100). Such elastomeric materials comprise from about 30% to about 60% by weight of adhesive layer 31, preferably from about 35% to about 50% by weight
30 of adhesive layer 31. The water soluble hydro-

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colloids and optional water swellable cohesive strengthening agents are present at from about 20% to about 65% by weight of adhesive layer 31, preferably from about 30% to about 60% by weight of adhesive layer 31. Adhesive layer 31 also preferably includes as a plasticizer up to 10% by weight of mineral oil and up to 25% by weight of terpene resin.

The adhesive layer 31 varies from about 1 mil to about 10 mils in thickness and contains holes or pores of from about 10 microns to about 300 microns in size and a porosity of about 1 to about 100 cc/sec/in² as determined by ASTM D-726-71 method using Gurley Densometer 4110 at 4.89 inches of water Δ P.

Porous backing layer 32 can be formed of woven or non-woven fabric such as the rayon web described by Copeland in U.S. Patent 3,121,021, an open mesh polymeric substance such as an open mesh polyethylene or polypropylene or a polymeric foam such as polyurethane foam, polyethylene foam, etc., or a non-woven material made from polyester fibers, polypropylene fibers, nylon fibers, composite olefin fibers, or cellulose fibers which are commercially available.

These non-woven spun bonded materials are the preferred porous backing layers. The porous backing layer can vary in thickness from about 3 mils to about 20 mils.

Component C is prepared according to the procedure of U.S. Patent 3,121,021 when adhesive layer 31 is an acrylic type adhesive. When adhesive layer 31

is a mixture of elastomeric substances and hydro-
colloids, then component C is prepared by dispersing
the viscous or elastomeric pressure sensitive adhesive
materials, thermoplastic elastomers, water soluble
5 hydrocolloids, water swellable cohesive strengthening
agents, tackifiers, plasticizers, and other optional
ingredients in a hydrocarbon solvent such as toluene,
heptane, or hexane or mixtures thereof to form a slurry.
The slurry is then deposited, for example, by means of
10 a knife-over-roller, onto a web of silicone coated
release paper. The slurry is deposited at a wet
thickness of from about 5 mils to about 40 mils,
preferably about 10 mils thick. The release paper
having the adhesive layer 31 is then passed through
15 a drying tunnel, for example, a multi-zone hot air
oven, where it is dried to less than 1% by weight of
residual solvent. The air temperature and velocity
through the drying zone are controlled so that numerous
small bubbles are generated from the solvent evaporation
20 resulting in voids in the adhesive layer which provide
the desired microporosity. The dry adhesive layer is
then laminated to a web of porous backing material 32
suitably positioned so that the adhesive layer 31 is
pressed into intimate contact with the porous backing
25 material 32. Component C of the desired configuration
is then die cut from the web. The silicone coated
release paper is then stripped off that portion of
adhesive layer 31 which overlaps flange 21 of
coupling element B and film 12 of component A.

30 An alternate embodiment of the composite skin barrier
of this invention is shown in figure 6. In this embodiment,
component C is bonded directly to polymeric film layer 12 of
component A. Of course, as in the first embodiment, component
C extends beyond the borders of component A so that adhesive

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layer 31 contacts the skin a distance from the stoma while adhesive layer 11 contacts the skin contiguous with the stoma. Coupling element B is then permanently affixed by impulse heat welding or by use of
5 adhesives directly to porous backing layer 32 so as to encircle the starter hole 20. As shown in figure 6, component C may extend across all of polymeric film 12 in which case a starter hole would be included to align with starter hole 20. Alternatively,
10 component C may end directly beneath the area where flange 21 and rib 22 meet so that the skin barrier inside the coupling consists only of component A as in figure 1.

The composite skin barriers of this invention are used in conjunction with an ostomy pouch having a coupling element
15 designed to mate with coupling element B. As shown in figures 4 and 5, the pouch 40 includes a coupling member 44 of channel-shape seen in any radial cross-section and has a radially inner wall 53 and a radially outer wall 55. A rim 58 extends inwardly around the inner periphery of the wall 55 and,
20 together with the wall 53, defines a restricted annular mouth or entry 58A into which, in use, the rib 22 of coupling member B is pushed to connect the pouch to the skin barrier. Rim 58 cooperates with rim 24 in providing added mechanical security. Of course, the rib 22 is dimensioned to be gripped between the
25 channel walls. Coupling member 44 is sealed to pouch 40 around the stomal opening 46 by heat welding to surface 45. Coupling 44 is preferably of the same polymeric material as coupling B.

Figure 4 shows pouch 40 as a closed ended pouch of the type employed by most colostomates. Of
30 course, an open ended pouch having a drainable bottom opening

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as employed by ileostomates or a pouch having a tap valve may also be used in conjunction with the skin barrier of this invention.

5 Coupling member 44 includes two ear shaped projections having openings 49 for the attachment of a belt and projection 47 which serves as a grip in uncoupling the pouch from the skin barrier.

10 The exposed surfaces of adhesive layer 31 and adhesive layer 11 may be covered with silicone coated release paper which is removed just prior to use.

15 While the rib shaped coupling 22 has been shown as component B of the skin barrier and the channel shaped coupling 44 as part of the pouch, it is possible to reverse the coupling elements. Thus, channel shaped coupling member 44 could be affixed at surface 45 to polymeric film 12 or to porous backing layer 32 in the alternate embodiment and rib shaped coupling member 22 can be affixed to the pouch by sealing flange 21 around stomal opening 46. In this case, surface 20 45 may be extended outwardly to function as a flange which is then overlapped by adhesive layer 31.

The coupling element B in the skin barrier of this invention has been shown as having a circular shape. However, the rib member 22 could have other configurations provided, 25 of course, that the pouch coupling element corresponds. Also, component A has been shown as having a circular configuration and component C as having a rectangular configuration. Clearly, other geometric configurations could be employed.

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Also, while the composite skin barrier of this invention has been described as consisting of three components permanently affixed to one another, it is, of course, possible to
5 join components A and B as a single unit and attach component C separately at the time of use.

The following examples are illustrative of the invention.

10 Example 1

A skin barrier was prepared as follows:

Component A

An adhesive mass was prepared consisting of:

<u>Ingredient</u>	<u>Percent by weight of the adhesive layer</u>
-------------------	--

Polyisobutylene (Vistanex LM-MH)	40
20 Sodium carboxymethyl- cellulose	20
Pectin	20
Gelatin (powder)	20

25 A premix was prepared by blending 2 kg. of sodium carboxymethylcellulose, 2 kg. of gelatin and 2 kg. of pectin. The blended premix was added to a heavy duty sigma blade type mixer followed by the addition of 4 kg. of polyisobutylene. Mixing was continued until the blend was homo-
30 geneous (about 25 minutes).

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The resulting dough mass while hot and soft was extruded and flattened to 70 mils.

A sheet of polyethylene of 2 mils thickness was laminated onto one side and silicone coated

5 release paper on the other. The resultant mat was die cut into circular shaped wafers of about 2.5 inches in diameter having a center hole of about 0.5 inches in diameter.

Component B

10 A polyethylene coupling element as shown in figures 1 to 3 was prepared by injection molding. The circular rib 22 has a diameter of about 1.75 inches and a height of about 0.18 inches. The flange was affixed to the polyethylene film
15 of component A by ultrasonic welding.

Component C

A microporous adhesive mass was prepared consisting of:

20	<u>Ingredient</u>	Percent by weight of the microporous adhesive layer
	Polyisobutylene (Vistanex L-100)	20
	Polyisobutylene (Vistanex LM-MH)	18
	Sodium carboxymethyl- cellulose	18
	Gelatin (powder)	15

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<u>Ingredient</u>	<u>Percent by weight of the microporous adhesive layer</u>
-------------------	--

Terpene resin	20
5 Mineral oil	8.5
Butylated hydroxy- toluene	0.5

10 The above solids were dispersed in sufficient heptane to make a slurry containing 40% by weight of solids. The slurry was applied via a knife-over-roller onto silicone coated release paper to a wet thickness of 10 mils. The material was then passed through a multi-zone oven with a residence time of 5 - 10 minutes so as to reduce
15 the solvent content to less than 1%. The resulting dry adhesive layer was from about 2 to 3 mils thick and had a porosity of about 5 cc/sec/in². As the dry adhesive film emerged from the oven, it was laminated to a web of spunlaced polyester fiber (DuPont
20 Sontara 8003) coming from a roll suitably positioned so that the adhesive was pressed into intimate contact with the spunlaced material.

25 The resulting microporous tape was die cut into 4 inch squares having a center hole of about 2 inches. A portion of the silicone coated release paper around the center hole was stripped away and the microporous tape was pressed into contact with flange 21 of the coupling element.

30 The overall dimensions of components A and C and the diameter of circular rib 22 of component B were varied to obtain skin barriers usable with different size stomas.

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Examples 2 - 11

5 Following the procedure of Example 1 but
employing the following ingredients in adhesive
layer 11 of component A other skin barriers
within the scope of this invention are prepared.
The ingredients are listed in percent by weight
of the adhesive layer.

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Ingredient	2	3	4	5	6	7	8	9	10	11
Polyisobutylene (Vistanex IM-MH)	40	-	40	32	-	30	50	45	-	38
Polyisobutylene (Vistanex IM-MS)	-	45	-	-	36	-	-	-	45	-
Guar gum	60	25	30	-	-	25	25	25	25	28.5
Locust Bean Gum	-	-	-	-	25	-	-	-	-	-
Pectin	-	15	-	-	-	-	-	15	-	19
Karaya	-	-	-	20	-	-	-	-	-	-
Gelatin	-	-	-	20	-	-	-	-	-	-
Sodium carboxy- methylcellulose	-	-	12	20	20	20	25	-	15	-
Cross-linked sodium carboxymethylcellu- lose (Aqualon R)	-	-	18	-	-	15	-	15	15	-

[illegible]

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Examples 12 - 19

5 Following the procedure of Example 1 but
employing the following ingredients in micro-
porous adhesive layer 31 of component C other
skin barriers within the scope of this invention
are prepared. The ingredients are listed in
percent by weight of the adhesive layer.

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<u>Ingredient</u>	<u>12</u>	<u>13</u>	<u>14</u>	<u>15</u>	<u>16</u>	<u>17</u>	<u>18</u>	<u>19</u>
Polyisobutylene								
(Vistanex IM-MH)	-	20	25	-	20	-	25	-
Polyisobutylene								
(Vistanex IM-IS)	20	-	-	20	-	20	-	18
Guar gum	35	20	-	20	-	20	15	20
Locust Bean gum	-	-	-	-	25	-	-	-
Pectin	-	-	10	-	-	-	-	-
Karaya	-	-	-	10	-	-	-	-
Gelatin	-	-	10	-	-	-	-	-
Sodium carboxy-								
methylcellulose	-	-	10	10	10	10	16	13
Cross-linked sodium								
carboxymethylcellu-								
lose (Aqualon R)	-	15	-	-	10	10	-	-

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<u>Ingredient</u>	<u>12</u>	<u>13</u>	<u>14</u>	<u>15</u>	<u>16</u>	<u>17</u>	<u>18</u>	<u>19</u>
Starch-acrylonitrile graft copolymer (Grain Processing Corp. Polymer 35-A-100)	-	18	-	-	-	-	-	-
Cross-linked dextran (Sephadex CM-C50)	-	-	7	-	-	-	-	-
Terpene resin	20	-	15	20	15	20	20	20
Mineral Oil	8.5	8.5	7.5	8.5	6.5	6.5	8.5	8.5
Butylated hydroxytoluene	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Kraton 1107	-	-	15	-	-	13	-	-
Butyl rubber (077)	-	-	-	11	-	-	-	-
Polyisobutylene (Vistanex L-100)	16	18	-	-	13	-	15	20

CLAIMS

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1. A composite skin barrier
including a first component comprising an adhesive layer and an outer polymeric film said first component having a centrally located stomal opening adapted to fit the skin barrier around a stoma, a second component comprising a concentrically shaped coupling element including an outwardly extending flange wherein said flange is permanently affixed to the polymeric film of said first component in an area surrounding said stomal opening, and a third component comprising a microporous adhesive layer and an outer porous backing layer said microporous adhesive layer overlapping said coupling element flange and polymeric film and extending beyond the borders of said first component.
2. A skin barrier according to Claim 1 wherein said coupling element is a cylindrical rib extending in an upward direction perpendicularly from said flange.
3. A skin barrier according to Claim 1 wherein the adhesive layer of said first component comprises a homogeneous blend of one or more pressure sensitive natural or synthetic viscous or elastomeric adhesive substances which can optionally include one or more thermoplastic elastomers and having dispersed therein one or more water soluble hydrocolloid gums which can optionally include one or more water swellable or inert natural or synthetic fibrous

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cohesive strengthening agents and other optional ingredients selected from the group consisting of antioxidants, preservatives, and plasticizers.

4. A skin barrier according to Claim 3 wherein the adhesive layer of said first component comprises a homogeneous blend of from about 30% to about 70% by weight of a pressure sensitive substance selected from the group consisting of natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, and low molecular weight polyisobutylene and one or more optional thermoplastic elastomers selected from the group consisting of medium molecular weight polyisobutylene, butyl rubber, and styrene copolymers and having dispersed therein from about 35% to about 65% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethyl-cellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more optional water swellable or inert cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymer, purified wood cellulose, cross-linked dextran, and cotton.

5. A skin barrier according to Claim 4 wherein the adhesive layer of said first component comprises a homogeneous blend of from about 40% to about 50% by weight of low molecular weight polyisobutylene and one

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or more optional thermoplastic elastomers selected from the group consisting of medium molecular weight polyisobutylene, butyl rubber, and styrene isoprene copolymers and having dispersed therein from about 45% to about 60% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more water swellable or inert cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymer, cross-linked dextran, purified wood cellulose, and cotton.

6. A skin barrier according to Claim 5 wherein said first component comprises an adhesive layer consisting of a blend of about 40% by weight of polyisobutylene, about 20% by weight of sodium carboxymethylcellulose, about 20% by weight of pectin, and about 20% by weight gelatin and said polymeric film is polyethylene.

7. A skin barrier according to Claim 1 wherein said third component microporous adhesive layer has a porosity of from about 1 to 100 cc/sec/in² and comprises a homogeneous blend of one or more pressure sensitive natural or synthetic viscous or elastomeric adhesive substances which can optionally include one or more thermoplastic elastomers and having dispersed therein one or more water soluble hydrocolloid gums which can optionally

include one or more water swellable cohesive strengthening agents and other optional ingredients selected from the group consisting of antioxidants, preservatives, plasticizers, and tackifiers and said third component porous backing layer comprises woven or non-woven fabric, an open mesh polymeric substance, a polymeric foam, or a non-woven material made from polyester fibers, polypropylene fibers, nylon fibers, composite olefin fibers, or cellulose fibers.

8. A skin barrier according to Claim 7 wherein the microporous adhesive layer of said third component comprises a homogeneous blend of from about 30% to about 60% by weight of a pressure sensitive adhesive substance selected from the group consisting of natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, and low molecular weight polyisobutylene and one or more optional thermoplastic elastomers selected from the group consisting of medium molecular weight polyisobutylene, butyl rubber, and styrene copolymers, from about 20% to about 65% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more optional water swellable cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymers, and cross-linked dextran, up to

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10% by weight of mineral oil, and up to 25% by weight of terpene resin.

9. A skin barrier according to Claim 8 wherein the microporous adhesive layer of said third component comprises a homogeneous blend of from about 35% to about 50% by weight of a blend of low molecular weight and medium molecular weight polyisobutylenes having dispersed therein from about 30% to about 60% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more optional water swellable cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymer, and cross-linked dextran, up to 10% by weight of mineral oil, and up to 25% by weight of terpene resin.

10. A skin barrier according to Claim 9 wherein said third component comprises a microporous adhesive layer consisting of a blend of about 18% by weight of low molecular weight polyisobutylene, about 20% by weight of medium molecular weight polyisobutylene, about 18% by weight of sodium carboxymethylcellulose, about 15% by weight of gelatin, about 20% by weight of terpene resin, about 8.5% by weight of mineral oil, and about 0.5% by weight of butylated hydroxytoluene and said porous

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backing is spun bonded polyester fiber.

11. A composite skin barrier for use by ostomates including a first component comprising an adhesive layer consisting of a blend of about 40% by weight of polyisobutylene, about 20% by weight of sodium carboxymethylcellulose, about 20% by weight of pectin, and about 20% by weight of gelatin and an outer polyethylene film, said first component having a centrally located stomal opening adapted to fit the barrier around a stoma, a second component comprising a concentrically shaped coupling element including an outwardly extending flange with a cylindrical rib extending in an upward direction perpendicularly from said flange wherein said flange is permanently affixed to said polyethylene film of said first component in an area surrounding said stomal opening, and a third component comprising a microporous adhesive layer having a porosity of about 5 cc/sec/in² consisting of a blend of about 18% by weight of low molecular weight polyisobutylene, about 20% by weight of medium molecular weight polyisobutylene, about 18% by weight of sodium carboxymethylcellulose, about 15% by weight of gelatin, about 20% by weight of terpene resin, about 8.5% by weight of mineral oil, and about 0.5% by weight of butylated hydroxytoluene and a porous backing of spun bonded polyester fiber, said microporous adhesive layer overlapping said coupling element

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flange and polyethylene film and extending beyond the borders of said first component.

12. The skin barrier of Claim 11 wherein the adhesive layer of said first component is about 70 mils in thickness and said polyethylene is about 2 mils in thickness, and said microporous adhesive layer of the third component is from about 2 to about 3 mils in thickness and said porous backing layer of said third component is about 10 mils in thickness.

13. A composite skin barrier for use by ostomates including a first component comprising an adhesive layer and an outer polymeric film said first component having a centrally located stomal opening adapted to fit the skin barrier around a stoma, an intermediate component comprising a microporous adhesive layer and an outer porous backing layer said intermediate layer bonded to and covering at least a portion of the outer polymeric film of said first layer and wherein said intermediate component extends beyond the borders of said first component, and a coupling component including an outwardly extending flange wherein said flange is permanently affixed to said porous backing layer in an area surrounding said stomal opening.

14. A skin barrier according to Claim 13 wherein said coupling element is a cylindrical rib extending in an upward direction perpendicularly from said flange.

15. A skin barrier according to Claim 13 wherein the adhesive layer of said first component comprises a homogeneous blend of one or more pressure sensitive natural or synthetic viscous or elastomeric adhesive substances which can optionally include one or more thermoplastic elastomers and having dispersed therein one or more water soluble hydrocolloid gums which can optionally include one or more water swellable or inert natural or synthetic fibrous cohesive strengthening agents and other optional ingredients selected from the group consisting of anti-oxidants, preservatives, and plasticizers.

16. A skin barrier according to Claim 15 wherein the adhesive layer of said first component comprises a homogeneous blend of from about 30% to about 70% by weight of a pressure sensitive substance selected from the group consisting of natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, and low molecular weight polyisobutylene and one or more optional thermoplastic elastomers selected from the group consisting of medium molecular weight polyisobutylene, butyl rubber, and styrene copolymers and having dispersed therein from about 35% to about 65% by weight of one

or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more optional water swellable or inert cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymer, cross-linked dextran, purified wood cellulose, and cotton.

17. A skin barrier according to Claim 16 wherein the adhesive layer of said first component comprises a homogeneous blend of from about 40% to about 50% by weight of low molecular weight polyisobutylene and one or more optional thermoplastic elastomers selected from the group consisting of medium molecular weight polyisobutylene, butyl rubber, and styrene isoprene copolymers and having dispersed therein from about 45% to about 60% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more water swellable or inert cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymer, cross-linked dextran, purified wood cellulose, and cotton.

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18. A skin barrier according to Claim 17 wherein said first component comprises an adhesive layer consisting of a blend of about 40% by weight of polyisobutylene, about 20% by weight of sodium carboxymethylcellulose, about 20% by weight of pectin, and about 20% by weight gelatin and said polymeric film is polyethylene.

19. A skin barrier according to Claim 13 wherein said intermediate component microporous adhesive layer has a porosity of from about 1 to 100 cc/sec/in² and comprises a homogeneous blend of one or more pressure sensitive natural or synthetic viscous or elastomeric adhesive substances which can optionally include one or more thermoplastic elastomers and having dispersed therein one or more water soluble hydrocolloid gums which can optionally include one or more water swellable cohesive strengthening agents and other optional ingredients selected from the group consisting of antioxidants, preservatives, plasticizers, and tackifiers and said intermediate component porous backing layer comprises woven or non-woven fabric, an open mesh polymeric substance, a polymeric foam, or a non-woven material made from polyester fibers, polypropylene fibers, nylon fibers, composite olefin fibers, or cellulose fibers.

20. A skin barrier according to Claim 19 wherein the microporous adhesive layer of said intermediate component comprises a homogeneous blend of

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from about 30% to about 60% by weight of a pressure sensitive adhesive substance selected from the group consisting of natural rubber, silicone rubber, acrylonitrile rubber, polyurethane rubber, and low molecular weight polyisobutylene and one or more optional thermoplastic elastomers selected from the group consisting of medium molecular weight polyisobutylene, butyl rubber, and styrene copolymers, from about 20% to about 65% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, and gum karaya and one or more optional water swellable cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymers, and cross-linked dextran, up to 10% by weight of mineral oil, and up to 25% by weight of terpene resin.

21. A skin barrier according to Claim 20 wherein the microporous adhesive layer of said intermediate component comprises a homogeneous blend of from about 35% to about 50% by weight of a blend of low molecular weight and medium molecular weight polyisobutylenes having dispersed therein from about 30% to about 60% by weight of one or more water soluble hydrocolloids selected from the group consisting of sodium carboxymethylcellulose, pectin, gelatin, guar gum,

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locust bean gum, and gum karaya and one or more optional water swellable cohesive strengthening agents selected from the group consisting of cross-linked sodium carboxymethylcellulose, starch-acrylonitrile graft copolymer, and cross-linked dextran, up to 10% by weight of mineral oil, and up to 25% by weight of terpene resin.

22. A skin barrier according to Claim 21 wherein said intermediate component comprises a microporous adhesive layer consisting of a blend of about 18% by weight of low molecular weight polyisobutylene, about 20% by weight of medium molecular weight polyisobutylene, about 18% by weight of sodium carboxymethylcellulose, about 15% by weight of gelatin, about 20% by weight of terpene resin, about 8.5% by weight of mineral oil, and about 0.5% by weight of butylated hydroxytoluene and said porous backing is spun bonded polyester fiber.

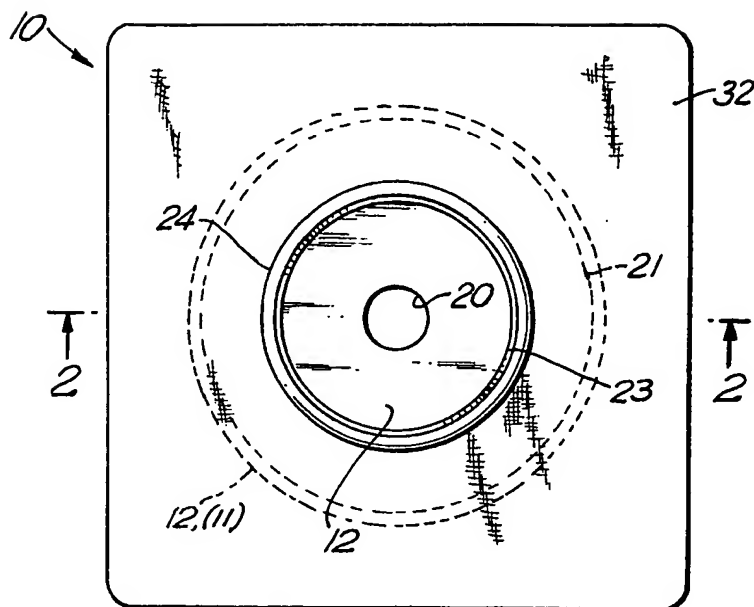


FIG. 1

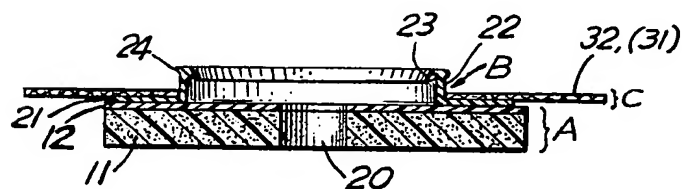


FIG. 2

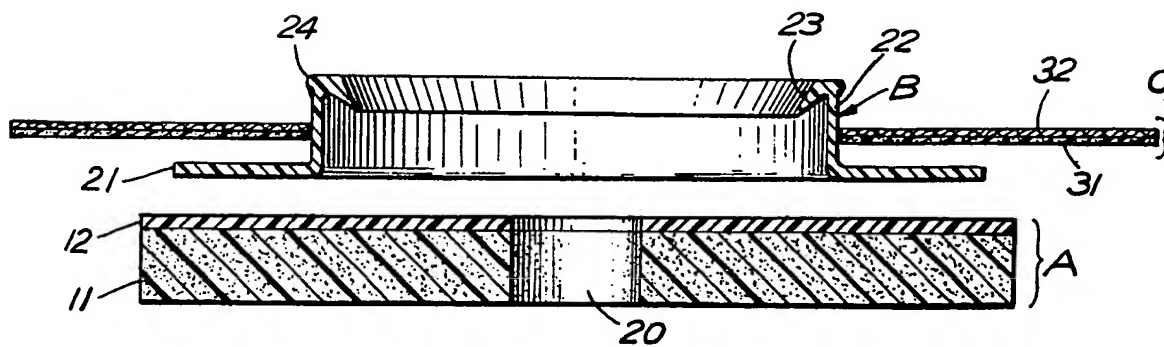


FIG. 3

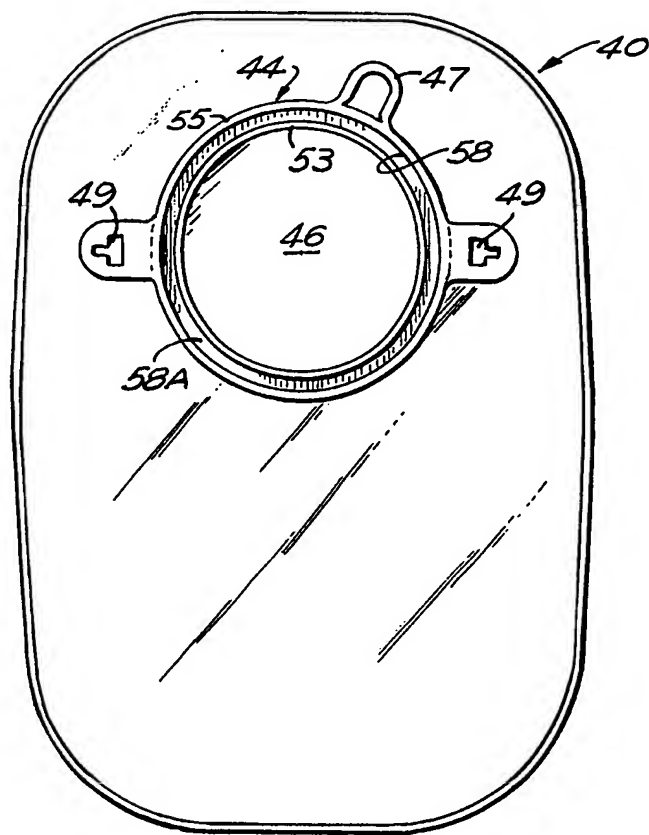


FIG. 4

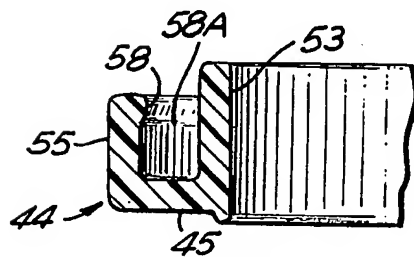


FIG. 5

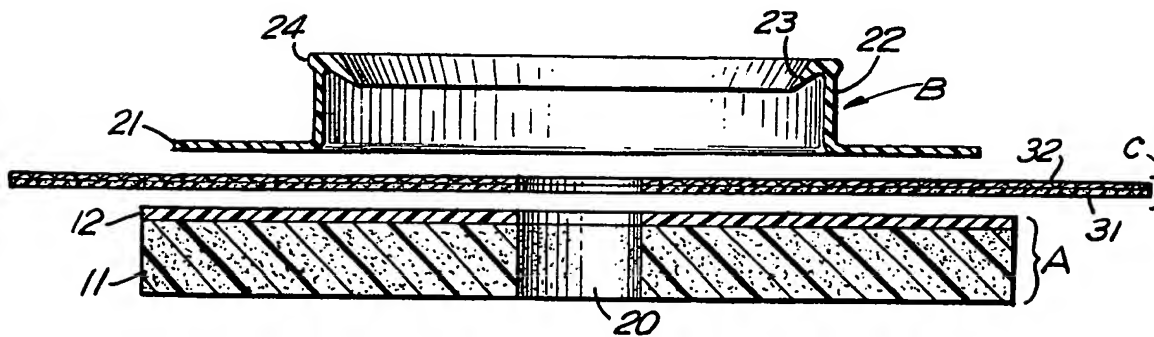


FIG. 6



European Patent
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EUROPEAN SEARCH REPORT

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Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 82305995.1
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 3)
A	EP - A1 - 0 024 253 (DE ZAEPFFEL) --		A 61 F 5/44
A	US - A - 3 814 648 (BRONDBERG) --		
A	US - A - 3 804 091 (NOLAN) --		
A	US - A - 3 712 304 (MARSAN) --		
A	GB - A - 839 818 (JACOBSEN & FREDERIKSEN A/S) --		
A	CH - A - 531 353 (MINNESOTA MINING AND MANUFACTURING COMPANY) ----		
			TECHNICAL FIELDS SEARCHED (Int. Cl. 3)
			A 61 F 5/00
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
VIENNA		28-02-1983	EBERLE
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